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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,470	12/03/2004	Aylwin Ng	007193-5	4015

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EXAMINER	
YAO, LEI	
ART UNIT	**PAPER NUMBER**
1642	
MAIL DATE	**DELIVERY MODE**
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,470	NG ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-34 and 43-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-34 and 43-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/9/2007, 3/16/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *PTO-90*.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group IX (claims 31-34) in the reply filed on 7/17/2007 is acknowledged.

The traversal is on the ground(s) that some of the groups are not independent or distinct and do not lack of unity of invention and also that the method of group IX is based on the results generated from use of the claims of III and IV. Applicants further argue that it is not the nucleic acid or polypeptide that is the special technical feature, it is the ability to first identify the type of NPC (which is defined in both Groups III and IV) and then to treat a subject based on that definition (Group IX).

These have been considered, but not found persuasive. The technical features of group III and IV are in vitro method of determining the type of NPC based on expression of nucleic acid (III) and polypeptide (IV) in nasopharyngeal cancer (NPC). Thus, group III and IV involve screening the expression of different genes in samples from different patients with NPC, while group IX is drawn to a method of treating NPC patient with a specific drug demethylation agent. The each group has unique technical features (different method steps and using different materials), which do not share with the others, for example, group III, a method of determining the type of NPC based on the expression of nucleic acids in the NPC patients, in which the expression of different nucleic acids from the patients would be detected by the technique using DNA probe for extracted RNA or DNA in the sample of the patients, no in vivo process is involved or claimed, no drug of demethylation or other anti-cancer agent is applied. However, the elected group IX, drawn to a method of treating a patient with NPC, in which claimed invention is required in vivo administering the agent and/or in combination with other chem- or radio-therapy. This method is not shared or overlapped with any method step of group III and IV. Thus, the unity among the group III, IV and IX is lacking. For this reason, the restriction requirement is deemed to be proper and is adhered to. The requirement is therefore made **FINAL**.

Claims 43-45 are added. Claims 31-34 and 43-45 are pending and will be examined on the merits.

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on 3/16/2007 and 8/9/2007 are/is considered by the examiner and initialed copies/copy of the PTO-1449 are/is enclosed.

Sequence Requirements

A first office action can be performed on this application, however, this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). This application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825. Although the claims in the instant application are not drawn to specific sequences, the disclosure contains sequences that need SEQ ID numbers on paragraph [0086] and [0092]. If these sequences have been submitted to the Office, Applicants need only insert the appropriate SEQ ID Nos based on the sequence listing. If these sequences are not part of the listing or have not submitted to the Office, then Applicants need to comply with the sequence rules. Applicant is reminded to check the entire disclosure to ensure that the application is in sequence compliance.

Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply (see attached form, PTO L90).

Specification

Specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on paragraph [0088]. Applicant is required to check entire specification and delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquires set forth in Graham V. john Deere Co., 383 U.S. 1, 148 USPQ 459 (1996), that are applied for establishing a background for determining obviousness under 25 U.S. 103 (a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or obviousness

Claims 31-33 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuratomi et al., (Eur Arch Otorhinolaryngol, vol 256, page S60-63, 1999) in view of Momparler et al., (anticancer Drugs, vol 8, page 358-6, 1997) as evidenced by ATCC product description.

Claims are drawn to a method of treating an individual with a nasopharyngal cancer (NPC) comprising administering to said individual a demethylation agent in association with a second cancer treatment (claim 31), wherein second cancer treatment is chemo- or radio-therapy (claim 32), wherein the demethylation agent is 5-aza-2-deoxycytidine (claim 33, 43), wherein NPC is type I (claims 44 and 45). The specification teaches that the type of NPC is defined based on WHO classification, in which type I NPC is differentiated squamous cell carcinoma with cellular keratin [0003].

Kuratomi et al., teach a method of treating a NPC patient by administering chemotherapeutic drugs ((5-fluorouracil) combined with vitamin A and/or radiotherapy (entire reference). Kuratomi et al., also teach that the NPC patients comprising undifferentiated, poorly differentiated, and moderately differenticiated squamous cell carcinoma (SSC) respond to the treatment differently, in which undifferentiated carcinoma (type II or III) respond better than more differentiated SSC (page 60 and 61 figure 1).

Kuratomi et al., do not teach treating NPC patient in combination with a demethylation drug comprising 5-aza-2-deoxycytidine.

Momparler et al., teach that the patients with lung squamous cell carcinoma are effectively treated with the demethylation drug, 5-aza-2-deoxycytidine (page 361-362, table 1 and figure 1).

Momparler et al., also teach lung squamous cell, NCI-H520, is sensitive to 5-aza-2-deoxycytidine and NCI-H520 is characterized as differentiated lung squamous cells with cellular karatin as evidenced by ATCC product description (page 2).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply the teaching of Momparler et al., to the teaching of Kuratomi et al., in order to advance the treatment for NPC patients with combined anticancer agent comprising 5-aza-2-deoxycytidine because Kuratomi et al., suggest that NPC patient is highly responsive to combined therapy (page s60, col 2) and Momparler et al., teach that differentiated squamous cell carcinoma is effectively treated with demethylation drug, 5-aza-2-deoxycytidine. One of ordinary skill in the art at the time the invention was made would have been motivated to replace one of combined anticancer agent in the therapy, such as vitamin A, in the method of Kuratomi et al., with 5-aza-2-deoxycytidine taught by Momparler et al., to specifically treat type I NPC patients because Momparler et al., teach that karatin positive squamous cell carcinoma cell is sensitive to the drug and Kuratomi et al., teach that the combined chemotherapeutic agents and/or radiation (without demethylation agent) has less effective to the moderately differenticiated squamous cell carcinoma (page S61, figure 1). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success to treat all types of NPC patients because combined methods of Kuratomi et al., Momparler et al., have shown the effective treatment for the NPC patients. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,
Examiner
Art Unit 1642

LY

SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice to Comply	Application No. 10502470	Applicant(s) Aylwin Ng	
	Examiner Lei Yao	Art Unit 1642	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: need SEQ ID numbers for sequences on paragraph 86 and 92.

Applicant Must Provide:

☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
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